5. 510(k) SUMMARY

OCT 23 2009

1. Submitter:

Interlace Medical Inc.
135 Newbury St
Framingham, MA 01701
Telephone: 508.875.1343, ext. 112

Contact: John J. Vozella, VP Clinical & Regulatory Affairs
Date Prepared: March 30, 2009

2. Device:

Trade Name: MyoSURE™ Hysteroscopic Tissue Removal System
Common Name: Hysteroscope and accessories
Classification Name: Hysteroscope and accessories
Class: II

3. Predicate Device:

Interlace Medical Hysteroscopic Morcellation System (K073690)
Gynecare Morcellex Tissue Morcellator (K061050)

4. Device Description:

The MyoSURE Hysteroscopic Tissue Removal System consists of the following procedural components:

- MyoSURE Control Unit
- MyoSURE Tissue Removal Device
- MyoSURE Foot Pedal

The MyoSURE Control Unit contains an electric motor and software controller that drives the MyoSURE Tissue Removal Device. The Control Unit motor is activated and deactivated by the MyoSURE Foot Pedal. The MyoSURE Tissue Removal Device is a tissue morcellator that is connected to the Control Unit via a flexible drive cable. The MyoSURE Tissue Removal Device features a rotating/reciprocating (2mm OD) cutter blade encased in a (3 mm OD) outer tube (i.e. morcellator). The morcellator's cutter blade is controlled by a drive system that enables simultaneous rotation and reciprocation of the cutter. The cutter is also connected to a vacuum source which aspirates resected tissue through a side-facing cutting window in the device's outer tube. Distension fluid and resected tissue are transported from the MyoSURE Tissue Removal Device to a tissue trap and vacuum canister via a tube protruding from the proximal end of the Tissue Removal Device. The MyoSURE Hysteroscopic Tissue Removal System is

compatible with commercially available fluid management systems and may be used with hysteroscopes that have a straight 3 mm working channel.

5. **Intended Use:**

The MyoSURE™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

6. **Comparison of Characteristics:**

The principles of operation and primary functional specifications of the MyoSURE Hysteroscopic Tissue Removal System are identical to those of the predicate Interlace Medical Hysteroscopic Morcellation System device, K073690. Each device employs a sterile, single use, disposable straight surgical morcellator for tissue removal. A foot pedal controls activation and deactivation of the motor which powers the morcellator in both devices. The MyoSURE morcellator is identical to the predicate morcellator in that it consists of a rotating and reciprocating inner tube or cutter that is totally contained within a stationary outer tube and has a vacuum tube fitting at its proximal end to enable aspiration of resected tissue. The MyoSURE inner tube or cutter rotates and reciprocates at a fixed rate that is identical to the predicate device. The MyoSURE cutter blade tip design is identical to that of the predicate device and the outer tube design of both devices incorporates a side-facing "cutting window" through which targeted tissue is pulled, cut, and moved back through the inner tube to a collection canister.

The MyoSURE Hysteroscopic Tissue Removal System's intended use is identical to that of the predicate Interlace Medical Hysteroscopic Morcellation System.

The MyoSURE Hysteroscopic Tissue Removal System is different from the predicate Interlace Medical Hysteroscopic Morcellation System device as follows:

- The MyoSURE Control Unit's electric motor, motor control software and electronic circuitry components have been modified from those found in the predicate device.
- The MyoSURE Tissue Removal Device is smaller, lighter and completely disposable and also features a more ergonomic hand piece design than the predicate device.
- The MyoSURE Tissue Removal Device's morcellator features a mechanical drive mechanism in the handle which is connected via a flexible drive shaft to an electric motor in the MyoSURE Control Unit while the predicate Interlace morcellator is driven by a mechanical drive mechanism and two separate electric motors, all of which are located in the handle of the device.
- The electric motor in the MyoSURE Control Unit is software-controlled.

- The MyoSURE Tissue Removal Device morcellator's cutting tube outer surface is now coated with Titanium Nitride (TiN) to mitigate galling potential of the cutter tube and outer tube; the predicate Interlace device's cutting tube outer surface is not coated.
- A vacuum sensor present in the predicate device has been eliminated in the MyoSURE™ Hysteroscopic Tissue Removal System.
- Instructions for use for the MyoSURE™ Hysteroscopic Tissue Removal System have been changed from the predicate instructions for use to reflect the new device's ergonomic design modifications.

7. Performance Testing:

The MyoSURE Hysteroscopic Tissue Removal System meets electrical safety and EMC standards. New patient contact materials in the MyoSURE device meet the biocompatibility requirements of ISO 10993-1 Biological Evaluation of Medical Devices. In addition, in-vitro testing demonstrated that the MyoSURE device performs equivalent to or better than the predicate Interlace Morcellator device.

8. Conclusion:

Based on the intended use, descriptive information and performance evaluation provided in this submission, the MyoSURE Hysteroscopic Tissue Removal System has been shown to be equivalent in technology, method of operation, functional performance and intended use to the predicate Interlace Medical Hysteroscopic Morcellation System device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

OCT 23 2009

Interlace™ Medical, Inc.
c/o Jonathan S. Kahan
Hogan & Hartson, LLP
555 Thirteenth Street, N.W.
WASHINGTON DC 20010

Re: K091100
Trade/Device Name: MyoSURE™ Hysteroscopic Tissue Removal System
Regulation Number: 21 CFR §884.1690
Regulation Name: Hysteroscope and accessories
Regulatory Class: II
Product Code: HIH
Dated: October 6, 2009
Received: October 6, 2009

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K091100

Device Name: MyoSURE™ Hysteroscopic Tissue Removal System

Indications For Use:

The MyoSURE™ Hysteroscopic Tissue Removal System is intended for hysteroscopic intrauterine procedures by a trained gynecologist to resect and remove tissue including submucous myomas and endometrial polyps.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K091100